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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,226	12/20/2001	Ranjani V. Parthasarathy	57313US002	9039

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EXAMINER

HANDY, DWAYNE K

ART UNIT PAPER NUMBER

1743

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/027,226		PARTHASARATHY ET AL.	
	Examiner		Art Unit	
	Dwayne K. Handy		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/22/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-28,30-55,62-67,77 and 78 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-28 and 30-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-55,62-67, 77 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/05, 5/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 50-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending Application No. 10/417,609 in view of Dusterhoft (6,451,260). This is a provisional obviousness-type double patenting rejection. This rejection remains in effect.

Claims 50-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-42 of copending Application No. 10/417,609 in view of Dusterhoft (6,451,260). This is a

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provisional obviousness-type double patenting rejection. This rejection also remains in effect.

The Examiner notes Applicant's desire to address these rejections upon indication of otherwise allowable subject matter (pages 14-15 of submission dated 3/11/05).

Inventorship

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 50-52, 64, 65, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,344,326) in view of Dusterhoft et al. (6,451,260).
6. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Mian et al. (6,319,469). Claims 54, 55, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Chisolm et al. (4,399,009).
7. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Kellogg et al. (6,632,399).

These rejections were made in the previous Office Action (mailed 12/14/04) and remain in effect. Please see Response to Arguments below.

Response to Arguments

8. Applicant's arguments filed 3/11/05 have been fully considered but they are not persuasive. Applicant has argued that Dusterhoft does not teach "solid hydrophilic particles of a hydrophilic solid support partially embedded within a hydrophobic matrix". In particular, Applicant has argued that paragraph 74 of Dusterhoft does not contain this feature. The Examiner respectfully disagrees and submits that paragraph 74 of Dusterhoft does indeed disclose "solid hydrophilic particles that are partially embedded within a hydrophobic matrix".

Applicant has submitted an exhibit that defines a matrix as "a surrounding substance within which something is contained or embedded". The Examiner agrees with this definition. The Examiner now refers to Paragraph 76 of Dusterhoft. Note the passages in bold.

(76) Without intending to be bound to theory it is believed that in generating the microporous element according to the present invention the following mechanisms are involved: When the nonsolvent diffuses into the layer of resin solution, the solubility of the resin is gradually decreased. As the limit of solubility is reached the resin begins to precipitate from the solution at individual points. The **precipitation of the resin proceeds at the points of initial precipitation. Ultimately, the solvent/nonsolvent is enclosed in large interconnecting enclaves in a solid matrix of resin (1).** The interconnecting enclaves form the liquid-permeable channels of the final microporous element. If a synthetic resin is used which **comprises both hydrophilic and hydrophobic segments (2), the hydrophobic segments will be forced towards each other and brought into contact with each other (3)** as the concentration of nonsolvent in the resin solution increases. There will be interactions between the hydrophobic segments of neighboring molecule chains, which result in the **formation of a crystalline hydrophobic backbone of the precipitated resin (4).** The **hydrophilic segments will be oriented towards the enclaves (5)** filled with solvent/nonsolvent. Accordingly, a

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microporous element is obtained where the **liquid-permeable channels are predominantly hydrophilic (6)**. This provides the benefit of biocompatibility. The term "biocompatibility" means that the three-dimensional structure of biopolymers, for example proteins, peptides, nucleic acids, oligonucleotides, polysaccharides or derivatives thereof, is maintained. The interphase forces are less destructive when the polymer surface is rich in hydroxyl, amide or ether groups.

The resin contains both hydrophilic and hydrophobic elements (bold passage #2). The resin is formed through precipitation (bold passages #1 and #4) which includes the formation of a crystalline hydrophobic backbone (#4). Therefore, the resin is a solid formed of a hydrophobic material. The solid matrix of resin **encloses** large interconnecting enclaves (#1 again). Therefore, the precipitated resin also has channels on the inside. These enclaves attract hydrophobic segments (#5) when the solvent is present. When the solvent is removed, the enclaves become channels of hydrophilic material comprised of the segments (#6). Therefore, the channels – and the hydrophobic material – are inside the resin. Given that the resin surrounds the channels and the resin portions away from the channel are hydrophobic, the Examiner believes this paragraph clearly teaches "solid hydrophilic particles of a hydrophilic solid support partially embedded within a hydrophobic matrix". The hydrophobic portion of the resin is a substance which surrounds solid hydrophobic particles (i.e. segments) contained in the enclaves (channels).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
August 20, 2006


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